IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

SCOTT PURCEL and PAMELA PURCEL, individually, and as Next Friend of B.P, a Minor,	§	
	§	
	§	CIVIL ACTION NO.
Plaintiffs,	§	3:07-CV-1777-M
	§	
v.	§	
	§	
ADVANCED BIONICS CORPORATION and ASTRO SEAL INC.,	§	
	§	
Defendants.		

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Advanced Bionics Corporation's Motion for Judgment on the Pleadings. For the reasons set forth below, the Motion is **DENIED**.

I. STATEMENT OF FACTS

B.P., a minor, is deaf. To allow B.P. to hear, in July of 2005, surgeons implanted into B.P.'s ears a cochlear ear device, the HiRes90k, manufactured by Defendant Advanced Bionics Corporation ("Bionics"). The safety and efficacy of the HiRes90k are the focal point of Plaintiffs' suit, which asserts claims for negligence, strict liability, fraud, and breach of warranty.

Plaintiffs' suit centers on a single component of the HiRes90k— a "feed-thru" used to connect the device's internal electrical circuitry to its external components. Defendant Astro Seal, Inc. ("Astro Seal") manufactured the feed thru in B.P.'s cochlear units. Although the HiRes90k failed to resolve B.P.'s deafness, Bionics assured Plaintiffs that the device conformed to manufacturing specifications and was not malfunctioning. However, in September of 2004, Bionics issued a voluntary recall of all HiRes90k devices containing Astro Seal feed-thrus. Although the recall covered only non-implanted devices, Plaintiffs elected to have B.P. undergo surgery to remove his two cochlear implants. Bionics tested those units and determined that the

moisture levels in them were 2.159% and 3.0312%—well above the maximum moisture level of .5% provided in the manufacturing specifications and approved by the Food and Drug Administration ("FDA").

A. Violations of Federal Requirements

1. Premarket Approval

The HiRes90k is a Class III device under the FDA's regulatory scheme. Therefore, prior to its sale to consumers, any modification affecting its safety or effectiveness, including any change in the facility manufacturing such a device, must receive FDA approval. 21 U.S.C. § 360e(d)(6)(A)(i) (2006); 21 C.F.R. § 814.39(a)(3) (2008). Other modifications requiring FDA approval include changes in the "performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." 21 C.F.R. § 814.39(a)(6). A Class III device sold without the requisite FDA approval is "adulterated." 21 U.S.C. § 351(f) (2006).

In July of 2003, Bionics obtained premarket approval for Pacific Aerospace & Electronics, Inc., to manufacture the feed-thrus for the HiRes90k. Subsequently, Bionics contracted with another company, Defendant Astro Seal, to manufacture the feed-thrus. Plaintiff alleges that Bionics failed to notify the FDA of its new supplier, and that Astro Seal altered the device's mechanical configuration and made changes to the length, composition, and "firing" process for the glass used in the feed-thrus. These modifications allegedly altered the glass's thermal properties, impacting its rate of expansion when exposed to heat.

2. Current Good Manufacturing Practices Requirements

The FDA requires manufacturers of Class III devices to comply with Current Good Manufacturing Practices ("CGMP") and considers Class III devices not satisfying CGMP

requirements as "adulterated" under 21 U.S.C. § 351(f), (h). *See* 21 C.F.R. § 814.39(a). Plaintiffs point to inspection reports and warning letters issued by the FDA to Bionics which document multiple violations of CGMP requirements between 2001 and 2005. These violations allegedly focused on moisture problems in the HiRes90k's internal circuitry—issues also allegedly found in Bionics' internal audits.

3. FDA Enforcement Action

In November of 2006, the FDA filed suit against Bionics and its President and Chief Executive Officer, Jeffrey H. Garner, for violations of CGMP and premarket approval requirements. The FDA's Complaint alleged that Bionics violated federal laws by failing to notify the FDA of its new feed-thru supplier, and by failing to validate the continued safety and effectiveness of its cochlear implant by conducting appropriate testing. The Complaint also claims that excessive moisture in the HiRes90k exposed patients to the risk of device failure, corrective surgery, and further hearing loss.

B. Plaintiffs' Claims

The Amended Complaint asserts claims for fraud, negligence, strict liability, and breach of express and implied warranties made by Bionics to Plaintiffs. Bionics' Motion seeks to dismiss Plaintiffs' strict liability and implied warranty claims.

Plaintiffs' strict liability claim is that under state law, the HiRes90k devices implanted in B.P.'s ears were defective, because they were adulterated under 21 U.S.C. § 351(f), (h) because: (1) Astro Seal was not an approved manufacturer of the feed-thrus in the HiRes90k; (2) Bionics did not obtain premarket approval for design modifications made to the HiRes90k; and (3) manufacturing processes for the HiRes90k did not comply with CGMP requirements.

Plaintiffs' claim against Bionics for breach of its implied warranty of merchantability is that B.P.'s cochlear units were "unfit for their ordinary purposes" under TEX. BUS. & COM. CODE ANN. § 2.314(b)(3) (Vernon 2003), because they were adulterated products under 21 U.S.C. § 351(f), (h).

II. ANALYSIS

A. Legal Standard

A defendant is entitled to judgment on the pleadings when the plaintiff fails to "state a claim upon which relief can be granted." Fed. R. Civ. 12(c), (h)(2). A motion for judgment on the pleadings under Rule 12(c) is subject to the same standard as a motion to dismiss under Rule (12)(b)(6). *Johnson v. Johnson*, 385 F.3d 503, 529 (5th Cir. 2004) (citing *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co*., 313 F.3d 305, 313 n.8 (5th Cir. 2002)). Accordingly, a court must liberally construe the pleading in favor of the plaintiff, and all well-pleaded facts in the complaint must be taken as true. *See Campbell v. Wells Fargo Bank, NA.*, 781 F.2d 440, 442 (5th Cir. 1986). A plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. *Bell Atlantic Corp. v. Twombly*, ___U.S. ___, 127 S.Ct. 1955, 1964-65 (2007). Factual allegations must be sufficient to raise a non-speculative right to relief which is plausible on its face. *Id.* at 1965; *Reliable Consultants, Inc. v. Earle*, No. 06-51067, 2008 U.S. App. LEXIS 3102, at *8 (5th Cir. Feb. 12, 2008).

B. Preemption

Bionics contends that Plaintiffs' strict liability and implied warranty claims are preempted by the Medical Devices Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq*. The MDA expressly preempts state law "requirements" that are "different from, or in addition to, any

requirement" relating to safety or effectiveness applicable to the device under federal law. 21 U.S.C. § 360k(a) (2006). In *Riegel v. Medtronic*, the Supreme Court held that common law duties, including those arising under state tort and contract law, constitute "requirements relating to safety or effectiveness," and thus are subject to preemption under the MDA. ___ U.S. ___, 128 S.Ct. 999, 1007-1008 (2008). The relevant issue here is whether Plaintiffs' strict liability and implied warranty claims impose duties on medical device manufacturers "different from, or in addition to" those arising under the MDA, triggering preemption.

1. Strict Liability

The Court first determines whether Texas law regarding strict liability imposes duties "different from, or in addition to" those imposed by the MDA. Plaintiffs contend that B.P.'s cochlear units were defective and unreasonably dangerous products under Texas law. To prevail on such a theory, a plaintiff must prove that: (1) the defendant placed a product into the stream of commerce, (2) which was in a defective or unreasonably dangerous condition, and (3) there was a causal connection between the defect and the plaintiff's injuries or damages. *See Helen of Troy v. Zotos Corp.*, 511 F.Supp.2d 703, 721 (W.D. Tex. 2006); *Houston Lighting & Power Co. v. Reynolds*, 765 S.W.2d 784, 785 (Tex. 1988). The dispositive issue is not whether Texas tort law duties are, *in the abstract*, "different from, or in addition to" the federal requirements applicable to Class III devices, but whether the Plaintiffs are asserting claims under state law which impose requirements different from those arising under federal law.

Here, Plaintiffs' strict liability claims are predicated solely on violations of federal law. B.P.'s cochlear units were allegedly defective because they were adulterated within the meaning of 21 U.S.C. § 351 (f), (h), having been manufactured in violation of CGMP and premarket approval requirements. In *Medtronic, Inc. v. Lohr*, the Supreme Court concluded that state law

claims predicated on violations of federal law were not preempted. 518 U.S. 470, 495 (1996). There, the plaintiffs claimed that a pacemaker manufactured by the defendant was defective under Florida law, because it violated federal regulations applicable to Class III devices. The Court initially observed that, under Florida law, strict liability required proof that defendant's product was unreasonably hazardous, and that no similar federal requirement existed. However, the Court noted that differences in the applicable federal and state requirements did not interfere with the federal regulatory scheme and, therefore, preemption was not warranted. Because the plaintiffs' state law claims were predicated solely on violations of federal regulations, compliance with the relevant federal requirements would effectively absolve the defendant from liability under state law. As the Court explained in *Lohr*:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations . . . created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Id. Thus, under *Lohr*, the MDA does not preempt state law claims which are predicated solely on violations of federal law.

In *Riegel v. Medtronic*, the Supreme Court revisited the preemption principles announced in *Lohr*. 128 S.Ct. at 1011. Significantly, however, the Court expressed approval of the holding in *Lohr* relevant here: the MDA does not preempt state law claims which are premised solely on violations of federal law. Quoting *Lohr*, the Court stated:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Id. at 1011 (internal citations omitted). Guided by the Supreme Court's pronouncements in *Lohr* and *Riegel*, this Court concludes that the MDA does not preempt Plaintiffs' claims under strict liability, which are predicated solely on violations of federal law.

2. Implied Warranty of Merchantability

Likewise, Plaintiffs' state law claim for breach of the implied warranty of merchantability is predicated solely on violations of federal law. To prevail on a claim for breach of the implied warranty of merchantability, a plaintiff must prove that: (1) the defendant sold or leased the product to the plaintiff; (2) the product was unmerchantable; (3) the plaintiff notified the defendant of the breach; and (4) the plaintiff suffered injury. *Polaris Industries, Inc. v. McDonald*, 119 S.W.3d 331 (Tex. App.—Tyler 2003, no pet.). A product is "unmerchantable" if it is "unfit for its ordinary purposes." TEX. BUS. & COM. CODE ANN. § 2.314(b)(3) (Vernon 2003). A product which is inadequate for its intended purpose or which is unreasonably dangerous is unfit for its ordinary purposes. *See, e.g.*, *Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 665 (Tex. 1999); *Church & Dwight Co., Inc. v. Huey*, 961 S.W.2d 560, 569 (Tex. App.—San Antonio 1997, pet. denied).

Plaintiffs claim that B.P.'s cochlear units were unfit for their ordinary purposes because they were adulterated under 21 U.S.C. § 351. The Court's preemption analysis with respect to Plaintiffs' strict liability claim applies with equal force here. *See In re Medtronic, Inc.*, 465 F.Supp.2d 886, 897 (D. Minn. 2006) (concluding that the MDA did not preempt plaintiffs' claim for breach of the implied warranty of merchantability under a state provision substantively

identical to the Texas provision); 21 C.F.R. § 808.1(d) (excluding from preemption state "requirements of general applicability where the purpose of the requirement relates to other products in addition to devices (e.g. requirements such as . . . the Uniform Commercial Code (warranty of fitness))."). [1] Although the duties underlying Plaintiffs' implied warranty claims potentially differ from the relevant federal requirements, enforcement of those claims would not interfere with the federal regulatory scheme for medical devices, since Defendants' compliance with the applicable federal requirements would preclude liability under state law, as was the case in *Lohr*. Because dismissal of Plaintiffs' claims for breach of the implied warranty of merchantability would not serve the policies underlying preemption, preemption is not warranted here.

CONCLUSION

For the foregoing reasons, Defendant's Motion for Judgment on the Pleadings is **DENIED**. Plaintiffs are permitted to assert claims against Defendants for strict liability and breach of the implied warranty of merchantability, but solely to the extent such claims are predicated on violations of federal law.

SO ORDERED.

August 13, 2008.

BARBARA M. G. LYNN
UNITED STATES DISTRICT JUDGE
NORTHERN DISTRICT OF TEXAS

[1] In *Riegel*, the Supreme Court considered, but did not decide, whether § 808.1(d) governed the scope of MDA's preemption provision. The Court stated, "All in all, we think that § 808.1(d)(1) can add nothing to our analysis but confusion. Neither accepting nor rejecting the proposition that this regulation can properly be consulted to determine the statute's meaning; and neither accepting nor rejecting the FDA's distinction between general requirements that directly regulate and those that regulate only incidentally; the regulation fails to alter our interpretation of the text insofar as the outcome of this case is concerned." 128 S.Ct. at 1011.